

**REMARKS**

Claims 56-58, 61-65, 67-76, and 78-81 are pending in the application. Claims 56, 71 and 78 are independent.

Claims 56, 64 and 81 are amended. Support for the amendment can be found throughout the specification. No new matter is added.

Amendment to claim 56 is a broadening, rather than a narrowing amendment. Therefore, no reduction in available scope of equivalents under the Doctrine of Equivalents should attach by virtue of this amendment.

Reconsideration and favorable action are respectfully requested.

**I. Claim Rejections - 35 USC § 112**

1. Claims 56-58, 61-65 and 67-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In particular, the Examiner notes that "including a chelating agent" (present claims 56 and 71) is a concept that was not present in the specification as originally filed. Therefore it is considered new matter. The Examiner further advises Applicants that the issue here is not whether particular instances of calcium chelating agent are found, but rather whether the concept of any chelating agent was present in the specification as originally filed. The Examiner contends that support for any chelating agent was not present in the specification as originally filed. The specification as originally filed contains the following disclosures concerning chelating agents:

- (i) "...The matrix comprises a thickening agent, an agent for stabilizing the hydrogen peroxide-containing compound, a pH adjusting agent 25 and a calcium chelating agent." (page 4, lines 23-25);
- (ii) "...a calcium chelating agent is included in the composition to prevent precipitation of calcium ions. (Table 1-4)" (page 6, lines 1-4);
- (iii) "...examples of calcium chelating agents include any of the calcium chelating agents known in the art" (page 6, lines 8-9);
- (iv) "...calcium chelating agents may prevent this precipitation of calcium ions with the associated observed improvement of tooth bleaching effect." (page 6, lines 17-18);
- (v) "...more particularly 8-9.5 that includes a calcium chelating agent " (page 7, line 11).
- (vi) "...positive effect of the calcium chelating agent on tooth bleaching..." (page 14, line 1).

The above disclosures, however, do not provide adequate support for any chelating agent. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The Examiner is guided in his opinion that Applicant has not adequately describe the presently claimed subject matter by the MPEP at § 2163-2163.05. In particular, while Applicant's specification as originally filed contained a teaching of calcium chelating agents. Applicants now claim a chelating agent. Because such represents a genus that were not previously set forth or that would have been immediately envisaged by one skilled in the art to immediately envisage the product

claimed from the disclosed process. See e.g., *Fujikawa v. Wattanasin*, 93 F. 3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996)" (Emphasis added), see MPEP § 2163(I)(A). Also, "See also *In re Smith*. 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) ('Whatever may be the viability of an inductive-deductive approach to arriving at a claimed subgenus, it cannot be said that such a subgenus is necessarily described by a genus encompassing it and a species upon which it reads.' (Emphasis added))." see MPEP § 2163.05(II).

Considering the teachings provided in the specification as originally filed, the Examiner finds that Applicants have failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicants had possession of the concept of a "chelating agent". A chelating agent that has two coordinating atoms is called bidentate; one that has three, tridentate; and so on. EDTA, or ethylenediaminetetraacetate, one of the claimed "chelating agents" is a common hexadentate chelating agent. There is no teaching in the instant specification as to how one would choose a chelating agent, other than the calcium chelating agents set forth as in (i)-(vi) above.

Applicant respectfully traverses the rejection:

While it is true that a calcium chelating agent is fully disclosed and taught, as noted by the Examiner, the Examiner is ignoring the paragraphs that discuss only chelating agents, and not just calcium chelating agents. For example, see relevant portions of paragraphs [0025], [0027] (as published and cited below) and Table 1:

"[0025] The formulations below utilized ultrapure components to avoid destabilization caused by metal ion contaminants. The chelating agent used here is one of disodium EDTA (1C), citric acid (1B), and sodium acid pyrophosphate (1F).

[0027] The chelating agents used here are EDTA and sodium acid pyrophosphate."

These disclosures of chelating agents are not just specific to calcium chelating agents, but to chelating agents in general. Applicant respectfully submits that the above cited paragraphs and table definitely provide sufficient support for a chelating agent in the claims. However, in the interest of advancing prosecution, Applicant has amended claim 56 and reserves the right to present the pre-amended claims at a later time. The present rejection is now moot. Favorable action is respectfully requested.

2. Claim 81 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding the "mixing baffle" of claim 81, the Examiner notes that the claim states "The dosage delivery unit of claim 78 wherein the static mixer includes a mixing baffle." It is unclear to the Examiner how the "mixing baffle" differs from the static mixer. Turning to the instant specification on page 7, lines 22-24, it states that the mixing of the two components can be readily achieved using a multi-component tube containing a baffle, otherwise known in the art as a static mixer. The way the claim is stated, one is led to believe that the baffle is a separate component comprised in the static mixer, however the instant specification describes it as one and the same. Clarification is required.

Applicant respectfully submits that there is no ambiguity in the claim as submitted. As noted before, a static mixer includes many different versions, including those with a mixing baffle. This is clearly stated in the specification as cited by the Examiner. At the same time, while a mixing baffle can itself be a version of a static mixer, versions of a static mixer are not mutually exclusive, i.e., they can be combined to make another static mixer. Therefore, a mixing baffle can also be part of a static mixer even if it is also known as a static mixer itself.

However, in the interest of advancing prosecution, claim 81 has been amended. The rejection is now moot. Reconsideration is respectfully requested.

## **II. Claim Rejections -35 USC § 103**

Claims 56-58, 61-65, 67-76 and 78-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christina-Beck et al. U.S. Patent No. 5,766,574 in view of Spehar et al. U.S. Patent No. 4,753,536.

Christina-Beck et al. teach a dual component whitening dentifrice composition (see abstract). The peroxide is *inter alia* sodium percarbonate (a hydrogen peroxide containing compound) (column 3, lines 11-12) and further comprises thickeners, such as block copolymers having a molecular weight of 4000 (column 3, lines 47-67), water in an amount of from 5 to 30% (column 3, lines 42-46), and chelating agents such as sodium acid pyrophosphate (column 4, lines 1-10). It does not teach a stabilizing agent, however, it is noted that the stabilizing agent instantly claimed in claim 63 is sodium acid pyrophosphate, which is present in the composition of Christina-Beck as a chelating agent. "Products of identical chemical composition (i.e. sodium acid pyrophosphate) can not have mutually exclusive properties." A chemical composition

and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims (i.e. a stabilizing agent) are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a prima facie case of unpatentability of Spada's polymer latexes for lack of novelty.").

The pH of the formulation is in the range of 5 to 8, which overlaps and partially encompasses claims 58 (pH greater than 5.5), claim 67 (pH within a range of between 6 and 10), claim 68 (pH within a range of between 7 and 10) and claim 69 (pH within a range of between 8 and 9.5).

Christina-Beck et al. differs in that it does not teach an alkaline pH-adjusting agent per se. However, the pH of the dentifrice partially overlaps and encompasses the pH range of the instant claimed dosage delivery unit as noted above. The criticality of the specific alkaline pH-adjusting agents has not been disclosed. In the absence of any criticality and/or unexpected results of the instantly claimed alkaline pH-adjusting agents of claim 62, the instant invention is considered obvious.

Christina-Beck et al. does not teach the amount of water to be at least 70% water by weight, based on the weight of the mi (claim 61). It teaches water in the peroxide component in an amount between 5 — 30% (column 3, lines 42-46) and in the abrasive component in an amount between 10 and 20% (column 4, lines 40-41) to total about 15 to 50% water. As anyone of ordinary skill in the art will appreciate, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves no more than

the application of routine skill in the art of chemical engineering. See, only as exemplary, the dicta of *In re Aller* 105 USPQ 233. Similarly, the determination of optimal values within a disclosed range is generally considered obvious. See, only as exemplary, the dicta of *In re Boesch* 205 USPQ 215. For these and other self-evident reasons, it would have been obvious to add water greater than 70%.

Regarding the static mixer of the device, Christina-Beck et al. differs in that there is not a mixing baffle/static mixer disclosed, however, Spehar et al. teach a dispensing mixer for the storage and mixing of separate materials comprising a syringe with separate compartments that discharge from a common nozzle. The Nozzle assembly comprises a static mixing element that is caused to rotate by the ingress of material fed through the nozzle (see abstract). Since the static mixer was well known it would have been obvious to employ a static mixer to mix the dual component composition of Christina-Beck et al since it teaches that the components are "maintained separate from the other until dispensed and combined for application to teeth requiring whitening" (see abstract).

The Examiner further notes that in holding an invention obvious in view of a combination of references, there must be some suggestion, motivation or teaching in the prior art that would have led a person of ordinary skill in the art to select the references and combine them in the way that would produce the claimed invention. This motivation may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. Here, filtered through the prior art references and the nature of the problem to be solved, Christina-Beck disclosed that components are "maintained separate from the other until dispensed and combined for application to teeth requiring whitening" (see

abstract), Spehar et al. teach a dispensing mixer for the storage and mixing of separate materials comprising a syringe with separate compartments that discharge from a common nozzle and comprises a mixing baffle for mixing the separate materials. The particular known technique of a mixing baffle attached to a dispensing container was recognized as part of the ordinary capabilities of one skilled in the art. One of ordinary skill in the art would have been capable of applying this known technique to the dentifrice of Christina-Beck et al. that was ready for improvement and the results would have been predictable to one of ordinary skill in the art. The gap between the prior art and Applicant's system is simply not so great as to render the system nonobvious to one reasonably skilled in the art.

Applicant respectfully traverses the rejection.

First, Applicant wish to correct a word processing error made in the last response. After the word "That" in the last response to the 35 U.S.C. 103(a) rejection, and before the wordings "is hind sight construction, which is not permitted", Applicant accidentally left out the phrase, "even if Christina-Beck et al. patent is available as a reference". Applicant apologizes for the omission.

Second, Applicant has doubled checked the available information and would like to clarify this point further. The present patent application was filed on November 1, 2001, and "is a continuation of U.S. Patent Application No. 09/054,156, filed April 12, 1998, now U.S. Patent No. 6,312,670; which in turn is a divisional of U.S. Patent Application No. 08/719,569, filed September 25, 1996, now U.S. Patent No. 5,922,307; which claims priority from U.S. Provisional Application No. 60/004,258, filed September 25, 1995; each of which are incorporated herein by reference." See priority claim for the present application. Therefore, the priority date of the present application is prior to that of the Christina-Beck et al. patent. Thus, based on the information available to the



Application No.: 10/039,935

Customer No.: 53,096

Response to Second Office Action After RCE, dated November 20, 2007

Applicant, Christina-Beck et al. cannot constitute a proper citation for the rejection and the rejection is moot, unless the Examiner is aware of other data that is not immediately apparent to the Applicant.

Third, since the primary cited reference is not a proper reference, the rejection of claims 56-58, 61-65, 67-76 and 78-81 under 35 U.S.C. 103(a) as being unpatentable over Christina-Beck et al. U.S. Patent No. 5,766,574 in view of Spehar et al. U.S. Patent No. 4,753,536 is overcome. Favorable action is respectfully requested.

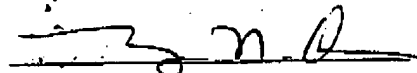
### III. CONCLUSION

The applicant believes that this Amendment addresses all of the points raised in the Office Action, and requests reconsideration and allowance of the present application, with pending claims 56-58, 61-65, 67-76, and 78-81.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact the undersigned at 310-845-8501.

Dated: February 4, 2008

Respectfully submitted,



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